

Application of: Kirschner, Mitchell I.  
Serial No.: 10/714,156  
Response to June 17, 2004 Office Action

### **REMARKS**

The Applicant respectfully requests that the pending claims 41,42,61,62,81, and 82 be canceled from the application and new claims 83 through 85 be entered. No new matter is introduced by this amendment.

In response to the Office Action dated June 17, 2004 , Applicant enters the following remarks:

The Examiner rejected the then pending claims under 35 U.S.C. 103(a) as being unpatentable over Hermelin et al. (U.S. Patent No. 6,258,846) or Abbruzzese (U.S. Patent No. 6,077,828), each in view of acknowledged prior art Opheim (U.S. Patent No. 6,346,231), Manufacturing Chemist & Aerosol News and Cuca (U.S. Patent No. 4,656,231.) In noting that the application is only an indirect continuation in part, the Examiner asserted that the Applicant was not entitled to the May 27, 1999 filing date of Serial No. 09/320,559 application for any of the claims as they appeared to contain subject matter that was not disclosed or enabled in the Serial No. 09/320,559.

The Applicant maintains that one group of previously presented claims in Ser. No. 10/714,156 were in fact disclosed and enabled by the '559 application and are thus entitled to the May 27, 1999 filing date as summarized below in Table One. The Applicant further maintains that the currently amended claims summarized below in Table Two now also meet the disclosure and enablement requirement and are also entitled to the May 27, 1999 filing date of the 09/320559 Application. The Applicant has cancelled claims 41,42,61,62,81, and 82. Language

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that supports each of the claims listed below can be found in the specification of the '559 application as outlined in the following table.

**Table One. Previously Presented Claims Supported by the 09/320559 Application**

Claim # in 10/714,156	Supporting Language in 09/320559	Comments
23	<u>Fatty Acids</u> : Page 33, Lines 16-24. <u>Calcium Compounds</u> : Page 33, Lines 1-15. <u>Soft Gelatin Shell</u> : Page 27, Lines 7-24. Page 28, Lines 1-9	
24, 25, 44, 45,	<u>Fatty acids from various listed marine sources</u> : Page 33, Line 24. Page 34, Lines 8-12. Page 36, Lines 15, 20, 21.	All specific fish oils in claim 25 are listed on Page 34 of '559
26, 46	<u>Fatty acids from various listed plant sources</u> : Page 33, Line 24. Page 34, Lines 1-7. Page 36, Lines 15-20.	
31	<u>Essential fatty acids, essential fatty acid precursors, and fatty acid derivatives</u> : see Page 33, Line 24. Page 34, Lines 1-12. Page 36, Lines 15-21. <u>Calcium Compounds</u> : Page 33, Lines 1-15. <u>Soft Gelatin Shell</u> : Page 27, Lines 7-24. Page 28, Lines 1-9	Applicant argues that each of the essential fatty acids, precursors and derivatives were known to be included in the marine and plant oils specified at the time of the application. See discussion below.
32, 52, 72	<u>Omega-3, Omega-6 fatty acids</u> : see Page 34 Line 1-5 references to plant oil sources <u>known on 5/27/1999</u> as omega-3 and omega-6 fatty acid sources;	As for claim 31
34, 35, 36, 54, 55, 56, 74, 75, 76	<u>Omega-3 fatty acid precursors (Linolenic Acid)</u> : see Page 34 lines 6 flaxseed oil reference; <u>Omega-3 fatty acid derivatives (EPA and DHA)</u> : see Page 34 line 9-11 fish oil references <u>Omega-6 precursors (Linoleic Acid)</u> : see Page 34 line 3 soybean oil reference <u>Omega-6 derivatives (GLA, AA)</u> : see	Oils listed in parent application were well known sources of the indicated precursors and derivatives on 5/27/1999;

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	page 34 line 6 evening primrose reference (GLA); also page 34 line 9-11 references to fish oils (AA)	
40	<u>Folic Acid</u> : Page 31, Lines 20-24; also claims 42 and 43.	
51	Method for preparing a soft gelatin encapsidated viscous mixture supplement is taught on Pages 46,47; <u>Essential fatty acids, essential fatty acid precursors, and fatty acid derivatives</u> : see Page 33, Line 24. Page 34, Lines 1-12. Page 36, Lines 15-21.	Applicant argues that each of the essential fatty acids, precursors and derivatives were known to be included in the marine and plant oils specified at the time of the application. See discussion below.

**Table Two. Currently Amended and New Claims Supported by the 09/320559 Application**

27,47,67 (currently amended)	<u>Fatty acids form various listed plant sources</u> : Page 33, Line 24. Page 34, Lines 1-7. Page 36, Lines 15-20.	All specific plant oils in claim 27 are listed on Page 34 & 36 of '559 with the exception of linseed oil, now absent in currently amended claim 27.
28, 37, 48, 57, 68, 77 (currently amended):	<u>Calcium compounds</u> : Page 33, Lines 1-15.	All specific calcium compounds in claims 28, 37, 48, 57, 68, 77 are listed on Page 33 of '559 with the exception of di- and tricalcium phosphate and calcium threonate, now absent in currently amended claims.
29,30,38,39,49,50,58,59,69,70, 78,79 (currently amended):	<u>Calcium Compounds</u> : Page 45, Table II , Formula I and Formula II	The claims are currently amended to reflect the '559 specification.
33,53, 73 (currently amended):	<u>Omega-3 fatty acid precursors (Linolenic Acid)</u> : see Page 34 lines 6 flaxseed oil reference; <u>Omega-3 fatty acid derivatives (EPA and DHA)</u> : see Page 34 line 9-11	Oils listed in parent application were well known sources of the indicated precursors and derivatives on

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	fish oil references <u>Omega-6 precursors (Linoleic Acid)</u> : see Page 34 line 3 soybean oil reference <u>Omega-6 derivatives (GLA,AA)</u> : see page 34 line 6 evening primrose reference (GLA); also page 34 line 9-11 references to fish oils (AA)	5/27/1999; weight ratios are now omitted from the currently amended claims to conform to the '559 specification.
43 (currently amended):	Soft gelatin supplement preparation: in Example 3, Page 46, and 47	This clause was inadvertently omitted from previously presented claim; note inclusion in previously presented claim 51
63 (currently amended):	1) <u>Method of administering a nutritional supplement during pregnancy</u> : Page 27, L7-13 2) in a suspension, beneficial nutritionally, minimizes stomach upset, and increases the bioavailability of the nutritional compounds: Page 17, L10-24	
71 (currently amended):	1) <u>Method of administering a nutritional supplement during pregnancy</u> : Page 27, L7-13 2) in a suspension, beneficial nutritionally, minimizes stomach upset, and increases the bioavailability of the nutritional compounds: Page 17, L10-24 3) <u>Essential fatty acids, essential fatty acid precursors, and fatty acid derivatives</u> : see Page 33, Line 24. Page 34, Lines 1-12. Page 36, Lines 15-21.	Applicant argues that each of the essential fatty acids, precursors and derivatives were known to be included in the marine and plant oils specified at the time of the application. See discussion below.
83,84, 85 (new)	<u>Folic Acid</u> : Page 31, Lines 20-24; also claims 42 and 43.	

While the essential fatty acids, essential fatty acid precursors, and essential fatty acid derivatives were not explicitly disclosed in the '559 parent application, it was widely known and

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amply documented at that time that the plant and marine oils disclosed contained essential fatty acids, essential fatty acid precursors, and essential fatty acid derivatives. Similarly, omega-3 and omega-6 fatty acids, precursors and derivatives were not explicitly disclosed in the '559 parent application, but were also widely recognized and amply documented constituents of the cited marine and plant oils disclosed in that application. Representative references illustrating this point include Gerster, H in Int J Vitam Nutr Res. 1998;68(3):159-73 on the presence of omega-3 precursors in flaxseed and the omega-3 derivatives in fish oil, Fan and Chapkin in J Nutr. 1998 Sep;128(9):1411-4 on the presence of omega-6 derivatives in evening primrose oil, and Meydani et al in J Am Coll Nutr. 1991 Oct;10(5):406-28 on the presence of omega-6 precursors in soy and sunflower oil. Since it was well known at the time of the '559 parent application that the plant and marine oils cited therein were primarily composed of the elements in the amended claims 31-36, the Applicant argues that this subject matter was enabled, does not constitute new matter and is entitled to the May 27, 1999 filing date. Since the Hermelin and Opheim references follow the May 27, 1999 filing date of the '559 application, they are not prior art.

As noted previously, Serial No. 09/320, 559 with a filing date of May 27, 1999, precedes all but the Abbruzzese, Cuca and Manufacturing Chemist and Aerosol news references cited by the Examiner as a basis for rejection under 35U.S.C.103(a). Although the Abbruzzese reference does describe some of the components specified in the '559 application, it only specifies the use of capsules and omits any reference to soft gelatin capsules. Moreover, all of the compositions outlined in Abbruzzese target patients suffering from cancer-related cachexia and/or anorexia and include high levels of amino acids, which are contraindicated as dietary supplements for the

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pregnant and nursing women targeted in this application (See "Safety of Amino Acids Used in Dietary Supplements," an FDA sponsored study published July 1992). The Cuca reference teaches the use of concentrated calcium suspensions in a Polyethylene Glycol (PEG) vehicle for soft gelatin capsule encapsulation. In contrast to the Cuca reference, the '559 application teaches the suspension of calcium and other nutrients in plant and marine oils for soft gelatin capsule encapsulation. Since the physical, chemical and biological properties of PEG are distinct from those of the fish and marine oils specified in the '559 application, we argue that the substitution of plant and marine oils for PEG as calcium suspension vehicles is non-obvious. Cuca further underscores this point in contrasting the preferability of calcium suspensions in PEG over the vegetable oil suspensions of calcium disclosed in Stanley ("Soft Gelatin Capsules" pp. 404-420 of Lachman et al). Finally, the Manufacturing Chemist and Aerosol news citation simply discloses omega-3-fatty acid encapsulation in soft gelatin tablets. Omega-3 fatty acids are only one of several components that were disclosed and demonstrated to be combinable in the '559 application. The applicant concludes that the compositions and methods claimed in this application would not have been obvious to an individual of ordinary skill in the art based on the collective teachings of Abbruzzese, Cuca, and Manufacturing Chemist and Aerosol News references.

In Applicant's telephone interview with Examiner of April 8, 2003, Examiner indicated that "the proposed method claims with calcium tied into functional language would overcome prior art record subject to update of prior art search." While the Applicant maintains that the cited prior art can be overcome as argued above, method claims 63 and 71 have nonetheless been

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currently amended to link calcium (i.e., "at least one pharmaceutically acceptable calcium compound") to functional language (i.e., "in a suspension that is beneficial nutritionally, minimizes stomach upset, and increases the bioavailability of the nutritional compounds") to strengthen these method claims.

If any issue regarding the allowability of any of the pending claims in the present application could be readily resolved, or if other action could be taken to further advance this application such as an Examiner's amendment, or if the Examiner should have any questions regarding the present amendment, it is respectfully requested that the Examiner please telephone Applicant's undersigned attorney in this regard.

Respectfully submitted,

Date: \_\_\_\_\_

9/10/04



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